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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,223

05/12/2006

Lorenzo De Ferra

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EXAMINER

PUTTLITZ, KARL J

ART UNIT

PAPER NUMBER

1621

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/579,223

Applicant(s)

DE FERRA ET AL.

Examiner

Karl J. Puttlitz

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/12/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-31, 38 and 39 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Those steps of forming the compound of formula 6 from the compound of formula 3 are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The rejected claims fail to recite those essential steps for converting the compound of formula 3 to a compound of formula 6.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-39, 42 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 22, 40 and 41, the definition of "OTs" is unclear.

Claim 22 requires the preparation of compound 6 but prepares compounds of formula 3, so it is unclear what compound Applicant intends to prepare by the claim.

The claims recite "preferably", in connection, for example, with solvents (see claim 32), or tosyl compounds (claim 28). It is unclear what compounds or solvents Applicant intend to cover.

It is unclear what reactions Applicant intends by the term "the reaction" in claims 30 and 31.

Claim 32 recites removal of groups, subsequent reaction, and subsequent ion exchange. However, it is unclear if the claim requires these steps since the claim merely lists these steps and fails to positively recite these steps.

Claims 42 and 43 provides for the use of compounds but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 42 and 43 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

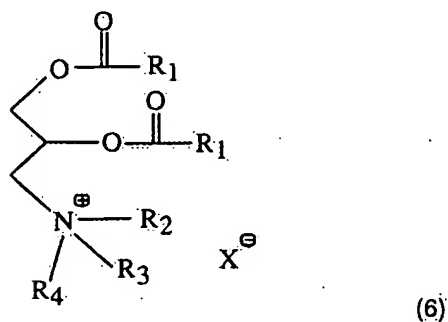
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

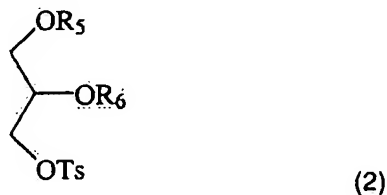
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-27, 32-39, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,897,355 to Eppstein et al. (Eppstein).

The rejected claims cover, inter alia, preparation of the following compounds:

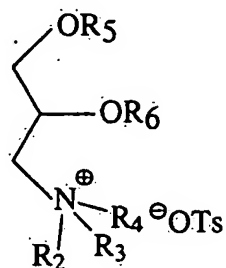


Characterized that a compound of formula 2:



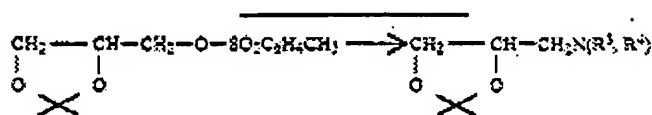
Is reacted with a tertiary amine to give a compound of the following formula:

Art Unit: 1621

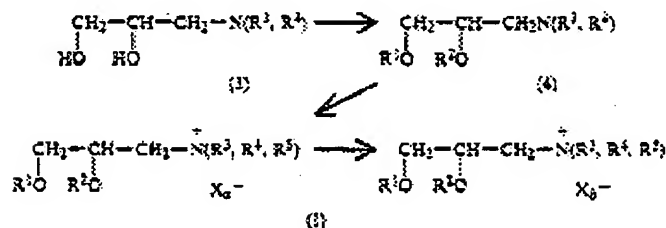


(3)

With regard to the above embodiments, Eppstein teaches the following reaction at column 20:



Eppstein also teaches the subsequent steps of claims 32-37:



see also description in

columns 21 and 22.

[see definitions in column 3, for example]

it is apparent from the above formulas that the specific compounds covered by the claim are particularly taught by the reference, see claim 39.

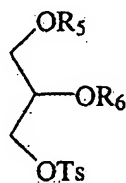
The difference between the process disclosed by Eppstein and the process covered by the rejected claims is that Eppstein fails to explicitly teach incorporation of an ammonium group. However, Eppstein teaches, in the same column, a subsequent step of preparing the ammonium compound. Therefore, those of ordinary skill would have been motivated to modify the disclosure of Eppstein to include direct incorporation

Art Unit: 1621

of a tertiary amine, since the patent teaches that the ammonium compound is the final product. Moreover, the choice of solvents in synthetic chemistry, in the absence of some unexpected benefit is routine, since those of ordinary skill would select solvents, such as alcohols, based on solubility of the reagents, and products. In this regard, purification by crystallization is also routine. Accordingly, the rejected claims are prima facie obvious in view of Eppstein since the reference teaches or suggest the elements of these claims with a reasonable expectation of success.

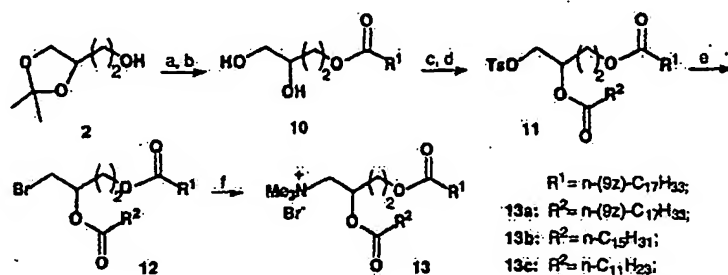
Claims 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eppstein in view of Ren et al., Tetrahedron Letters 40 (1999) 209-212 (Ren).

The rejected claims cover those embodiments covering the preparation of starting compound:



(2)

Eppstein fails to teach this preparation of compound. However, it is for this proposition that the examiner joins Ren. Specification, Ren teaches preparation of the tosylate compound, see reactions c and d in scheme 4 on page 211:



Scheme 4. (a) $R^1\text{COCl}$, TEA, cat DMAP, rt, 6h, 88%; (b) BCl_3 , -78°C to -25°C , 30min, 74% (c) TsCl , Py, cat DMAP, rt, 6h, 65%; (d) $R^2\text{COCl}$, TEA, cat DMAP, rt, 12hr, 80-87%; (e) LiBr , MEK, reflux, 1hr, 92%; (f) Me_3N -DMSO, rt, 72h, pressure tube, 30-36%.

Those of ordinary skill would have been motivated to modify Eppstein to include the preparation of compound 2 since Ren teaches that this compound can be prepared as claimed. Therefore, the rejected claim are prima facie obvious in view of Eppstein and Ren since the combination of these references teach or suggest the elements of these claims with a reasonable expectation of success.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl J. Puttlitz whose telephone number is (571) 272-


Art Unit: 1621

0645. The examiner can normally be reached on Monday to Friday from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at telephone number (571) 272-0602.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



KARL PUTTLITZ
PATENT EXAMINER